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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,330

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John N. Vournakis

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JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER

KIDWELL, MICHELE M

ART UNIT

PAPER NUMBER

3761

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/749,330	<b>Applicant(s)</b> VOURNAKIS ET AL.	
	<b>Examiner</b> Michele Kidwell	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31,37-39,41-46 is/are pending in the application.
- 4a) Of the above claim(s) 3,25,27,39,41,45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-24,26,28-31,37,38 and 42-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

After reconsideration, in conjunction with the applicant's remarks filed January 16, 2009, claim 1, as previously withdrawn by the Examiner will be rejoined and is herein considered on the merits.

The examiner notes that the rejoining of claim 1 is due to the Applicant's election of the femoral artery, and in turn the artery. As noted in the Election filed November 5, 2007, the non-elected species is the vein.

Claims 45 – 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim 1 is generic.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 2, 4 – 5, 7, 14 – 15, 21 – 22, 26, 28 – 29, 31, 37 – 38 and 43 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipshidze et al. (US 5,437,292).

With respect to claims 1 – 2, 4 and 43 – 44, Kipshidze et al. (hereinafter “Kipshidze”) discloses a method for treating a puncture in a femoral artery resulting from a cardiac catheterization procedure in a patient, comprising: a) applying topically over a catheter exit site a composition comprising an effective amount of a epinephrine, wherein the vasoconstrictor does not comprise a poly-.beta.-1 → 4 N-acetylglucosamine polymer or derivative thereof, and wherein the catheter exit site is contiguous with the catheter puncture in the femoral artery by 1-10 cm; and

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concurrently b) applying compression to the punctured vein or artery for at least one time interval of up to ten minutes as set forth in col. 8, lines 59 – 66.

The difference between Kipshidze and claims 1 – 2 is the provision that the composition is applied on the skin of a patient in need of such treatment.

It would have been obvious to one of ordinary skill in the art to provide the composition of Kipshidze to the compress that Kipshidze discloses to be used on the outer surface of the skin because the use of hemostatic patches (i.e., a compress including a hemostatic composition, such as that disclosed by Kipshidze, that is applied to the skin of a patient in need of such treatment) is well known in the art as acknowledged by applicant in [0005] of the instant specification.

Regarding claim 5, Kipshidze discloses a composition further comprising an anti-fungal or antibacterial agent as set forth in col. 8, lines 40 – 44.

As to claim 7, Kipshidze discloses a method further comprising a pharmaceutical carrier as set forth in col. 7, lines 54 – 60.

With reference to claim 14, Kipshidze discloses a method wherein the composition further comprises a coagulant as set forth in col. 7, lines 49 – 60.

With respect to claim 15, Kipshidze discloses a method wherein the patient is a human as set forth in col. 4, lines 4 – 6.

As to claims 21 and 22, Kipshidze discloses a method further comprising before step (a) the step of administering heparin to the patient as set forth in col. 8, lines 50 - 54.

With reference to claim 26, Kipshidze discloses a method wherein the compression is manual compression as set forth in col. 8, lines 53 – 59.

As to claims 28, 29 and 38, Kipshidze discloses a method wherein the compression is applied to the vein or artery proximal of the puncture or breach as set forth in the abstract and figures.

Regarding claim 31, Kipshidze discloses a method further comprising, repeating step (b) as set forth in col. 6, lines 11 – 21.

As to claim 37, Kipshidze discloses a method wherein the vein or artery is breached or punctured by a catheter as set forth in col. 4, lines 50 – 53.

Claims 6, 19 – 20, 23 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipshidze et al. (US 5,437,292) in view of Coury et al. (US 6,162,241).

The difference between Kipshidze and claim 6 is the provision that the composition further comprises collagen.

Coury et al. (hereinafter "Coury") teaches a composition further comprising collagen as set forth in col. 6, lines 49 - 56.

It would have been obvious to one of ordinary skill in the art to modify the composition of Kipshidze to include collagen because collagen activates or catalyzes the natural pathways of clotting as taught by Coury in col. 6, lines 49 - 56.

As to claims 19 – 20 and 42, see the rejection of claim 6.

The difference between Kipshidze and claim 23 is the provision that the composition further comprises protamine sulfate.

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Coury teaches a composition further comprising protamine sulfate as set forth in col. 7, lines 28 - 31.

It would have been obvious to one of ordinary skill in the art to modify the composition of Kipshidze to include protamine sulfate because the use of such acts as an antidote to anticoagulation as taught by Coury in col. 7, lines 28 – 31.

Claims 8 – 13, 16 – 18, 24 and 30 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipshidze et al. (US 5,437,292) in view of Cochrum et al. (US 2002/0197302).

The difference between Kipshidze and claim 8 is the provision that the composition is formulated as a solid.

Cochrum et al. (hereinafter "Cochrum") teaches a composition formulated as a solid as set forth in [0205], and specifically a gauze [0218].

It would have been obvious to one of ordinary skill in the art to formulate the composition of Kipshidze as a solid because the use of such rapidly arrests bleeding and promotes rapid clot formation as taught by Cochrum in [0205].

With respect to claims 9 – 13 and 18, see the rejection of claim 8.

As to claim 16, Cochrum discloses a composition applied as a film as set forth in [0224].

It would have been obvious to one of ordinary skill in the art to modify the composition of Kipshidze to apply it as a film or membrane because the flim/membrane is thinner and more flexible and therefore will have a decreased foreign body sensation as taught by Cochrum in [0224].

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As to claim 17, see the rejection of claim 16.

With reference to claim 24, Kipshidze discloses the method related to various types of procedures which may relate to the femoral artery as set forth in col. 3, line 61 to col. 4, line 4.

Cochrum teaches a similar concept relating to the femoral artery as set forth in [0235].

It would have been obvious to one of ordinary skill in the art to employ the method of Kipshidze to the femoral artery because the femoral artery is the largest artery which may result in rapid life-threatening blood loss if punctured and not immediately stabilized.

The difference between Kipshidze and claim 30 is the provision that the compression is applied with a compression bandage.

Cochrum et al. (hereinafter "Cochrum") teaches the compression is applied with a compression bandage as set forth in [0072].

It would have been obvious to one of ordinary skill in the art to employ a compression bandage in combination with the composition of Kipshidze because the use of such induces rapid blood coagulation while maintaining constant and direct pressure on the site as taught by Cochrum in [0072].

### ***Response to Arguments***

Applicant's arguments with respect to claims 1 – 31, 37 – 39 and 41 – 46 have been considered but are moot in view of the new ground(s) of rejection.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/  
Primary Examiner, Art Unit 3761